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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/833,134	04/11/2001	Leo J. Romanczyk JR.	5677-111	1617

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Clifford Chance Rogers & Wells LLP
200 Park Avenue
New York, NY 10166-0153

EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/833,134	Romanczyk JR et al.
Examiner	**Art Unit**
Christopher Tate	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *Sep 4, 2002*.

2a) [ ] This action is **FINAL.** 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *1, 3-10, 12-14, and 24-28* is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *2, 11, and 15-23* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____.
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [X] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [X] Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4 & 5*
4) [ ] Interview Summary (PTO-413) Paper No(s).
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Applicants' election with traverse of Group I, claims 2, 11, and 15-23, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that all the claims are directed to a cocoa oil product comprising phytosterols or a cocoa oil product comprising phytosterols and tocopherols and a method for their preparations. This is not found persuasive because, as discussed in the Office action of Paper No. 6, the cocoa oil product of Group I requires that it comprise two active ingredients (i.e., phytosterols and tocols such as tocopherols) whereas the cocoa oil of Group II (which has various therapeutic uses alone - i.e., does not necessarily require the presence of tocols for utility) only requires that it comprise one active ingredient (i.e., phytosterol), and the cocoa oil of Group III only requires that it comprise one active ingredient (i.e., ferulated phytosterols) - which is not necessarily required of either of the cocoa oil products of Groups I and II. In addition, the cocoa oil products of Group II (which is only defined as comprising phytosterols) and III (which is only defined as comprising ferulated phytosterols) can be made using numerous processes (including various conventional cocoa oil extraction/separation methods) which do not require any or all of the steps of the Group II process (in which both phytosterols and tocols are extracted from ground cocoa hulls with a suitable solvent as a step therein). Accordingly, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the three inventive Groups in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 11, and 15-23 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 11, and 15-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 depends from a non-elected claim and is, therefore, unclear. It is requested that the limitations of non-elected claim 1 be appropriately incorporated into claim 2.

Claims 11 and 15 recite the limitation "the phytosterols and tocols" in step (b) of each. There is insufficient antecedent basis for this limitation in these claims.

Claim 19 is rendered vague and indefinite by the phrase "purifying the cocoa oil by" the recited chromatographic means because, based upon the instant teachings, these chromatographic steps are not steps which would purify the oil, but instead appear to be analytical steps to assay the various components therein (see, e.g., pages 9-12 of the instant specification) and, therefore,

the chromatographic steps of claim 19 are outside the limitations of claim 15 which is a process of extracting a cocoa oil comprising phytosterols (and tocols) from cocoa hull, not a process of obtaining various constituents therefrom. Accordingly, it is strongly suggested that claim 19 be canceled in response to this Office action.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by El-Saied et al. (Zeitschrift Fuer Erna., 1981), or by Baskakova et al. (SU 1734748 - DWPI Abstract), or by Gavrilenko (Maslo-Zhir. Prom-st., 1977 - CAPLUS Abstract)

A cocoa oil extracted from cocoa hulls which comprises phytosterols and tocols such as tocopherols and tocotrienols is apparently claimed.

El-Saied et al. teach a fat (which reads upon an oil) which contains phytosterols such as those instantly claimed obtained from cocoa shells via hexane extraction followed by evaporation of the hexane therefrom, and that, based upon chromatographic analyses, the cocoa shell fat was similar in composition to cocoa butter (see, e.g., pages 145-146, Materials and Methods; and pages 149-150 under the heading *Unsaponifiable matter composition*). Based upon the teachings of the instant disclosure (see, e.g., claim 16), the reference cocoa shell fat (oil) obtained by hexane extraction would inherently comprise tocols such as tocopherols and tocotrienols, since hexane is disclosed (see, e.g., claim 16) to be a suitable solvent for extracting both of the claimed ingredients (phytosterols and tocols) in producing the claimed cocoa shell oil.

Baskakova et al. teach a cocoa husk (hull) oil which is added to a cosmetic formulation (see abstract). The cocoa husk (hull) oil taught by Baskakova would inherently contain the phytosterols and tocols instantly claimed since these are natural constituents of cocoa husk (hull) oil.

Gavrilenko teaches an oil extracted from cocoa husk (hulls) which does not contain an extraction solvent (see abstract). The crude and refined cocoa husk oil taught by Gavrilenko would inherently contain the phytosterols and tocols instantly claimed since these are natural constituents of cocoa husk (hull) oil. [With respect to the latter two references, please note that the patentability of a product does not depend on its method of production (see, e.g., MPEP 2113).]

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 11 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Warocquier-Clerout et al. (Int. J. Cosmetic Sci., 1992).

Warocquier-Clerout et al. teach a lipid extract (which reads upon an oil extract) termed ICSB of cocoa shell butter which is extracted therefrom (the starting cocoa shell butter is obtained from cocoa shells) using solvents including petroleum spirits (which is synonymous to petroleum ether: see, e.g., The Condensed Chemical Dictionary, 10th ed., 1981). Based upon subsequent fractionation thereof using silica gel column chromatography, the ICSB lipid/oil extract was shown by Warocquier-Clerout et al. to contain various phytosterols (such as instantly claimed and disclosed) as well as tocols (such as instantly claimed and disclosed) - see, e.g., page 39, *Synopsis*; page 40, second full paragraph; and pages 41-42 in the Result section under the heading *Preparation and Fractionation of ICSB* including Table 1 and Figure 1).

Accordingly, the cited reference discloses a cocoa shell oil extract product which appears to be identical to the presently claimed cocoa shell oil extract product, since it was obtained using similar extraction solvent(s) and it was shown by Warocquier-Clerout et al. to contain the same ingredients as instantly claimed.

In the alternative, even if the claimed cocoa shell oil extract product is not identical to the referenced cocoa shell oil extract product with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced cocoa shell oil extract product is likely to inherently possess the same characteristics of the claimed cocoa shell oil extract product particularly in view of the similar characteristics which they have been shown to share. Thus, the oil extract product would have been obvious to those of ordinary skill in the art within the meaning of U.S.C. 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the above rejection, in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claim Rejections - 35 U.S.C. § 103

Claims 2, 11, and 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over El-Saied et al. (Zeitschrift Fuer Erna., 1981) and Warocquier-Clerout et al. (Int. J. Cosmetic Sci., 1992), in view of Mueller (J. Dairy Sci., 1959) and Alander et al. (WO 99/63031), and further in view of Newton (EP 0861600).

Also claimed is a method of extracting a cocoa oil comprising cocoa phytosterols from cocoa hulls comprising grinding the cocoa hulls, treating the ground cocoa hulls with a solvent which extracts phytosterols and tocols, removing the solvent, and recovering the oil.

The primary references are relied upon for the reasons set forth above.

Neither primary reference expressly teaches grinding the cocoa hulls prior to extraction nor using some of the extraction solvents instantly claimed.

Mueller beneficially teaches the extraction of components from cocoa shells, whereby the cocoa shells are first ground prior to solvent extraction (see, e.g., page 754). The grinding of herbal parts including nuts and seeds prior to extraction, such as beneficially disclosed by Mueller, is notoriously well known in the art to advantageously facilitate the release of desired components therefrom during such solvent extraction by maximizing surface exposure.

Alander et al. beneficially teach that oils extracted from various herbals such as cocoa butter contain phytosterols, tocopherols, and tocotrienols which can be effectively extracted using suitable extraction solvents including nonpolar solvents such as hexane and petroleum ether (see, e.g., page 1, third paragraph; pages 7-8; page 10, third full paragraph).

It would have been obvious to one of ordinary at the time the claimed invention was made to modify the extraction procedures taught by the primary references in making a cocoa shell oil extract product via grinding the cocoa shells prior to solvent extraction based upon the beneficial teachings of Muller with respect to this notoriously well known practice, and to use and/or substitute other suitable extraction solvents such as petroleum ether vs. hexane based upon the beneficially teachings provided by Alander et al. with respect to their equivalency as extraction solvents of cocoa butter which El-Saied et al. teaches is very similar to cocoa shell fat (thus, the skilled artisan would have a reasonable expectation of success in extracting cocoa shells using such equivalent solvents to obtained phytosterols - as well as tocols).

It would also have been obvious to the skilled artisan to utilize micronized cocoa hulls as a starting material because Newton beneficially discloses that micronizing is a commonly means of breaking the outer husks/hulls of cocoa beans during processing (see, e.g., col 5, lines 46-52), making them a readily available source. The adjustment of particular conventional working conditions (e.g., removing the solvent by vacuum distillation, further exposing such an oil extract to chromatographic techniques, and/or using hulls from particular types of cocoa bean), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1651 is (703) 308-4242.

Christopher R. Tate
Primary Examiner, Group 1654